

REMARKS

The withdrawal of the rejection under 35 U.S.C. § 112 is acknowledged with gratitude.

Claims 1-5 remain rejected under 35 U.S.C. § 102(b) as anticipated by Mizumoto. This rejection is traversed.

The Examiner is of the opinion Mizumoto (col. 13, lines 62-65) teaches that a disintegrant may be added to the core granule in a coating process. However, Mizumoto does not teach anything like that.

In col. 13, lines 58-65, Mizumoto indicates that "additive agents may be used at an optional step in the production process of the intrabuccally dissolving compressed moldings, for example, when an active ingredient is mixed with a low moldability saccharide, **when a coating solution prepared by dissolving an active ingredient together with a high moldability saccharide in water is mixed**, or at a step before or after these steps" (emphasis added). It is not clear from this description, however, that a disintegrant may be added to the core granule in a coating process.

Mizumoto does state "when a coating solution prepared by dissolving an active ingredient together with a high moldability saccharide in water is mixed". If the Examiner's rejection is derived from this statement, it means that a disintegrant may be added to a coating solution. This, however, does not make sense.

Basically, a disintegrant is an additive agent for promoting disintegration or dispersion of a tablet in stomach or oral cavity into primary particles or individual particles through loosing adhesions between particles by absorbing water to swell. Once the disintegrant fully absorbs water, the function of the disintegrant cannot be fulfilled even after the disintegrant dries. Therefore, persons skilled in the art would not add a disintegrant to a coating solution.

On the other hand, in the present invention, the disintegrant basically is added on a core granule in a solid state (powder) (see Examples 1-12 of the present application), though the surface of the disintegrant comes in contact with water for a moment.

Additionally, in col. 12, lines 23-65, Mizumoto teaches six processes for producing the dissolving tablet of his invention. Among them, processes in which a coating step is described are the fifth and sixth.

The two processes are as follows:

"Fifth process

A low moldability saccharide (central core) is coated with a high moldability saccharide (first layer) and then coated with an active ingredient (second layer), and the resulting product is coated with a high moldability saccharide as a binder (third layer). The resulting granules are subjected to compression molding to obtain, for example, intrabuccally dissolving tablets.

Sixth process

A low moldability saccharide is coated with an active ingredient and the coated product is granulated with a high moldability saccharide. The resulting granules are subjected to compression molding to obtain, for example, intrabuccally dissolving tablets."

Neither of the two processes discloses or suggests that a core granule may be coated with a disintegrant. Also, Examples 1-19 of Mizumoto neither disclose nor suggest it. Therefore, persons skilled in the art who read Mizumoto would not have a motivation to try to coat a core granule with a disintegrant.

For the above reasons, applicants submit that the present invention is not anticipated by Mizumoto. In addition, applicants respectfully request an oral interview between the Examiner and the undersigned to further the prosecution of this application on the merits.

No fee is believed due from the filing of these Remarks. If a fee is due, however, please deduct that fee from our Account No. 50-1561.

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